8. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K120533

Applicant Information:

Date Prepared: February 20, 2012

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Device Information:

Trade Name	Common Name	Classification Name	Class
BigBoss™ Catheters	Percutaneous Catheters	Percutaneous Catheters	Class II
Mantaray™ Catheters	Percutaneous Catheters	Percutaneous Catheters	Class II
Mantaray™ Guidewires	Percutaneous Guidewires	Percutaneous Guidewires	Class II

Predicate Devices:

The BridgePoint Medical Peripheral System (comprised of the BigBoss™ Catheters, Mantaray™ Catheters, and Mantaray™ Guidewires) is substantially equivalent (and in some cases identical) in intended use and/or method of operation and technical aspects to the following predicate devices:

Device	Reference 510(k) Number
BridgePoint Medical (Coronary) System (comprised of the CrossBoss™ Catheter, Stingray™ Orienting Balloon Catheter, and Stingray™ Guidewire)	K102725
BigBoss™ Catheters	K113589
Mantaray™ Catheters	K111963 and K120129
Mantaray™ Guidewires	K111488

Device Description:
The BigBoss™ Catheters are single use, over-the-wire, disposable percutaneous catheters consisting of a full length coiled stainless steel shafts with PEBAX exteriors. The coiled shaft provides torque and makes it possible to push the device, and also provides a guidewire lumen. The device will be available in two models that are differentiated by the distal shaft stiffness. The distal shaft stiffness is specified by the distal grind dimensions of the coiled shaft component. The distal shaft transitions to an enlarged (1mm diameter) rounded distal tip. This stainless steel tip provides an atraumatic element that is intended to enhance the catheter's ability to move within the vasculature with reduced risk of arterial tissue engagement while providing radiopaque visibility. The BigBoss Catheter is hydrophilic coated to enhance lubricity. A torque device, coaxially positioned over the outer shaft at the proximal portion of the BigBoss Catheter, provides a comfortable user interface for device manipulation. The torque device (similar to a guidewire torque device) is positionable along the proximal portion of the catheter and includes a torsion release safety mechanism. This safety mechanism insures the torque input generated by the user remains within the torsional operating strength of the catheter shaft.

The Mantaray™ Catheters are single use, over-the-wire, disposable, dual lumen percutaneous catheters that facilitate the placement, support and steering of guidewires through the central guidewire lumen or through one of two sideports (identified by radiopaque markers). The sideports connect with the central guidewire lumen and facilitate guidewire steering (at an angle to the central lumen) by allowing the guidewire to exit the catheter. The catheter contains a small non-compliant balloon segment used for fluoroscopic orientation on the distal tip of the flexible shaft. The device will be available in two models that are differentiated by their balloon dimensions.

The Mantaray™ Guidewires are conventionally constructed, single use, disposable guidewires that consist of full-length stainless steel shafts with proximal PTFE coating where the distal portion of the stainless steel core is taper ground to provide distal flexibility. The distal portion also includes a coaxially positioned coil constructed of platinum/tungsten material for visibility under fluoroscopy. The coil is fixed to the stainless steel core wire via silver alloy solder and is coated with hydrophilic coating. The distal tip of the guidewire is supplied with an angled geometry which transitions to a conventional rounded tip. A short extension with an approximate diameter of 0.0035"-0.0065" (which is a monolithic extension of the core wire) extends approximately 0.007" distal of the rounded tip. The device will be available in four models that are differentiated by their distal tip stiffness and/or core wire diameter.

Intended Use:
The BridgePoint Medical Peripheral System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Comparison to Predicate Device(s):
The designs of the devices comprising the BridgePoint Medical Peripheral System are identical to their respective predicate devices. Bench testing was previously conducted using the BigBoss Catheter, Mantaray Catheter, and Mantaray Guidewire predicate devices in tests designed to address a chronic total occlusion application. Therefore, all prior bench performance testing (tensile, torque, kink resistance, trackability, corrosion, coating durability, particulate, balloon performance, dimensional, etc.) are directly applicable to this application. As well, all previous biocompatibility tests conducted for the aforementioned predicate devices are directly applicable to the devices that comprise the BridgePoint Medical Peripheral System as the devices are identical.

As demonstrated in both animal and human clinical evaluations, the devices used as a system function to enhance medical practice in facilitating the placement of guidewires or other interventional devices beyond chronic total occlusions. A 105-subject study was conducted in the United States that demonstrated the BridgePoint Medical Peripheral System could successfully allow the placement of guidewires and other interventional devices beyond chronic total occlusions with no significant increase in risk to the patient. A total of 66 subjects were treated with the BridgePoint Medical Peripheral System (16 roll-in subjects, 50 primary analysis subjects).

Performance Data:
The BridgePoint Medical Peripheral System has previously been evaluated using the following *in vitro* bench testing to confirm the performance characteristics:

- Tensile
- Burst
- Fatigue
- Inflation & Deflation Time
- Dimensional
- Hydration
- Guidewire Insert & Withdrawal
- Flexibility
- Trackability
- Guidewire Re-Direction
- Markerband Movement & Removal
- Markerband & Guidewire Interaction
- Kink Resistance
- Coating
- Torque
- Surface Defects
- Balloon Protector Removal
- Device Shaft Tip Deflection
- Corrosion Resistance
- Luer and Hub Tests
- Radiopacity, and
- Packaging

In vivo testing was also completed in accordance with 21 CFR Part 58, "Good Laboratory Practices for Nonclinical Laboratory Studies." The functional performance and safety of the BridgePoint Medical Peripheral System was evaluated in a porcine animal model. Devices were inserted into four arteries in each of six animals used for the evaluation. The vessels were evaluated angiographically followed by histology and pathology. Hematology and serum chemistry along with gross necropsy were also used for evaluations. There were no reported complications during each treatment. All six-animals survived the in-life period with no angiographic evidence of vessel injury or downstream embolism and no abnormal pathologic findings.

A 105-subject human clinical study was also conducted to confirm the BridgePoint Medical System would perform as intended in the treatment of patients with peripheral CTOs. A total of 17 investigators at 10 investigational sites participated in the study. A total of 129 devices were used in the study in 66 treated subjects (39 of the 105 subjects were screen failures and not treated with the BridgePoint Medical Peripheral System). The reported primary safety endpoint of subjects that experienced a major adverse event or MAE [defined as death, unplanned major amputation, perforation requiring percutaneous or surgical repair (i.e., stent placement or surgical intervention) or target lesion revascularization due to procedural complications (i.e., revascularizations following a failed procedure without complications are not included)] within 30 days of the procedure was 3.0% (2/66). The reported primary effectiveness endpoint data demonstrated an overall technical success rate of 85% (56/66). There were two reported perforations (3.0%).

Biocompatibility was previously established for the devices per the required ISO standards. Tests included Cytoxicity, Kligman Sensitization, Irritation – Intracutaneous Injection, Acute Systemic Cytotoxicity, Pyrogen, Hemocompatibility, *In Vitro* Hemocompatibility, Complement Activation (Direct) Assay, *In Vivo* Thrombogenicity Assay, and Unactivated Partial Thromboplastin Time evaluations. All tests demonstrated the materials and processes used in the design and manufacture of the devices are non-toxic and non-sensitizing to biological tissues consistent with the intended use.

All test results demonstrated the materials, manufacturing processes, and design of the BridgePoint Medical Peripheral System met the established performance criteria and will perform as intended.

Summary:

Based upon the intended use and descriptive information provided in this pre-market notification, the BridgePoint Medical Peripheral System has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BridgePoint Medical, Inc.
Ms. Jill Munsinger
13355 10th Ave N, Suite 110
Plymouth, MN 55441

SEP 18 2013

Re: K120533
Trade/Device Name: BridgePoint Medical Peripheral System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: February 21, 2012
Received: February 22, 2012

Dear Ms. Munsinger:

This letter corrects our substantially equivalent letter of May 22, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7. INDICATIONS FOR USE STATEMENT

510(k) Number: (TBA) K120533

Device Name: **BridgePoint Medical Peripheral System**

Indications For Use:

The BridgePoint Medical Peripheral System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120533